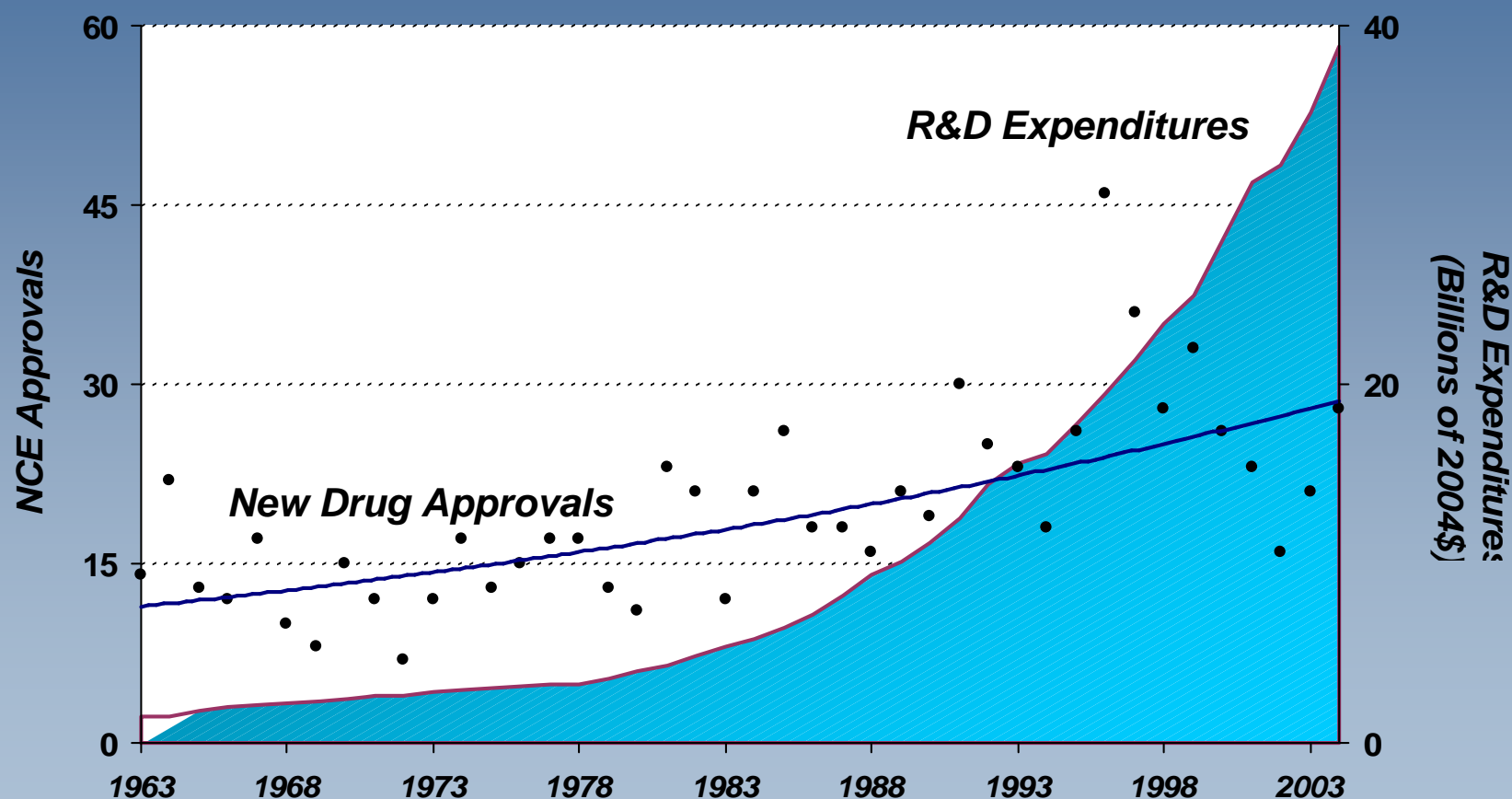


# *Costs and Returns for New Drug Development*

**Joseph A. DiMasi, Ph.D.  
Tufts Center for the Study of Drug Development  
Tufts University**

**FTC Roundtable on the Pharmaceutical Industry  
Washington, DC 10/20/06**

# New Drug Approvals Are Not Keeping Pace with Rising R&D Spending



*R&D expenditures are adjusted for inflation*

*Source: Tufts CSDD Approved NCE Database, PhRMA, 2005*

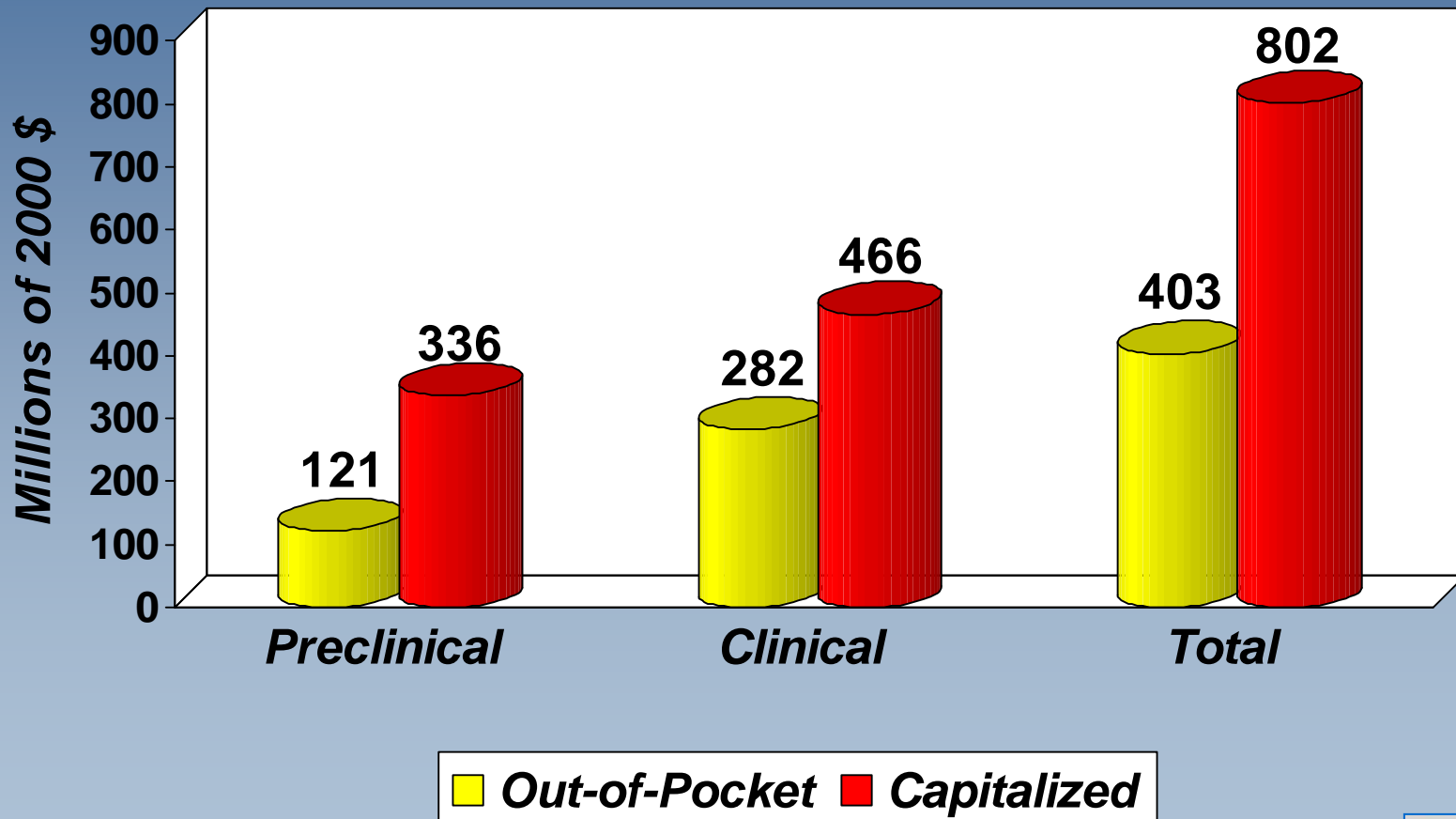


# Reported Productivity Declines in the Drug Industry: Is this New?

**“In 1960 the trade press of the U.S. drug industry began to refer to the last few years as constituting a “research gap,” commenting that the flow of important new drug discoveries has for some inexplicable reason diminished.”**

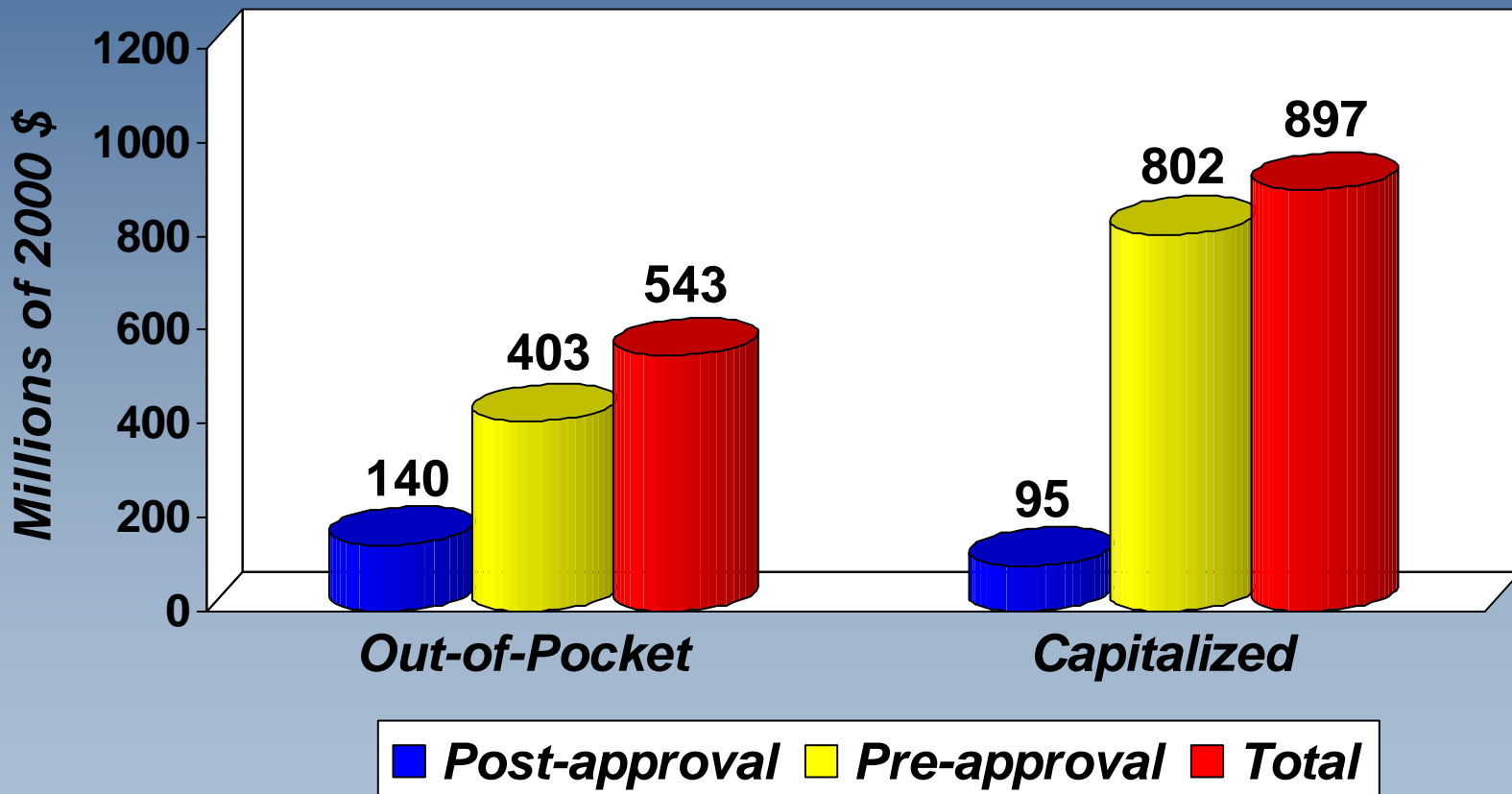
*Source: U.S. Senate, Report of the Subcommittee on Antitrust and Monopoly, 87<sup>th</sup> Congress, 1<sup>st</sup> Session, “Study of Administered Prices in the Drug Industry,” June 27, 1961, p.136*

# Out-of-Pocket and Capitalized Costs per Approved Drug



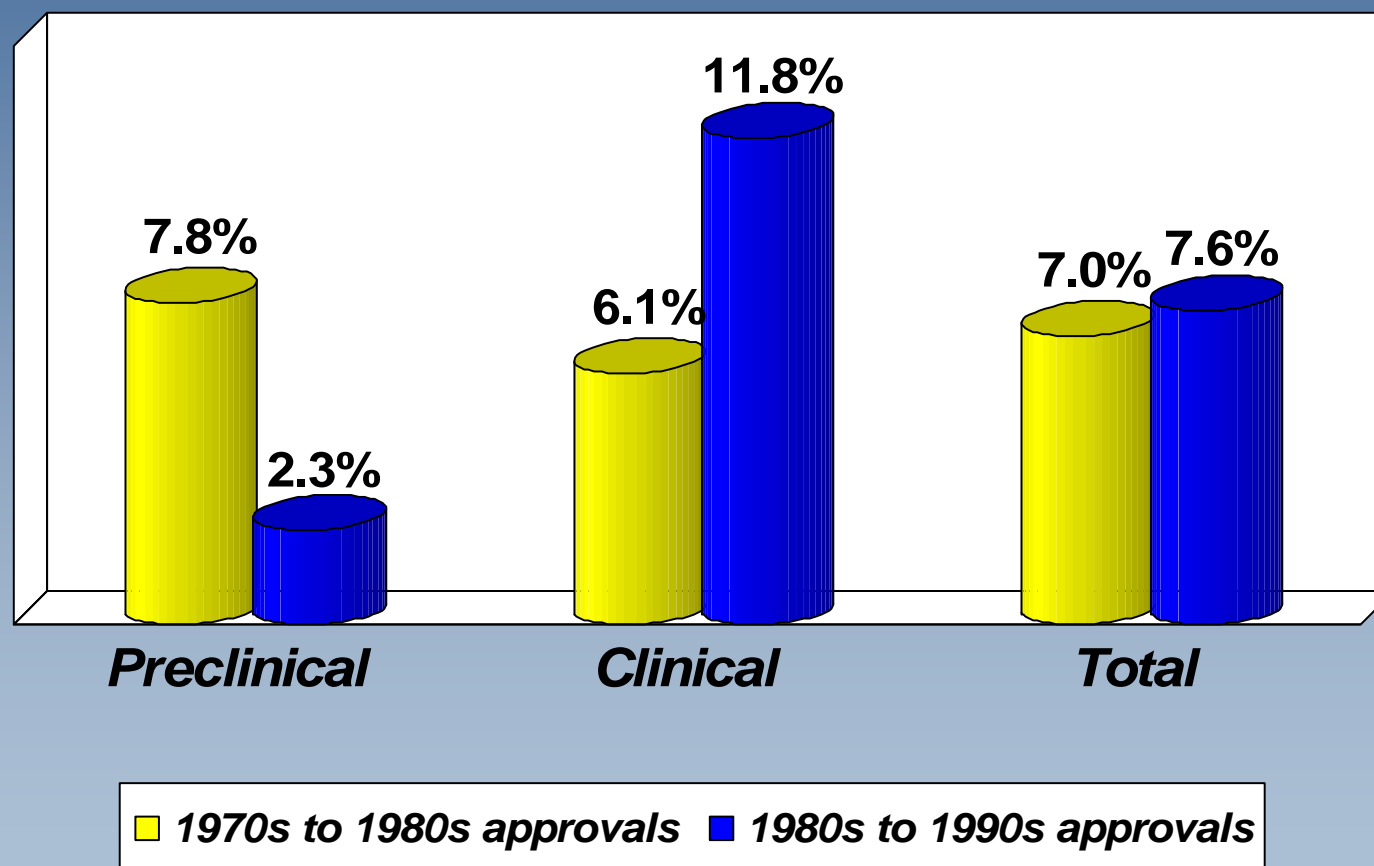
Source: DiMasi et al., *J Health Economics* 2003;22(2):151-185

# Pre-approval and Post-approval R&D Costs per Approved Drug



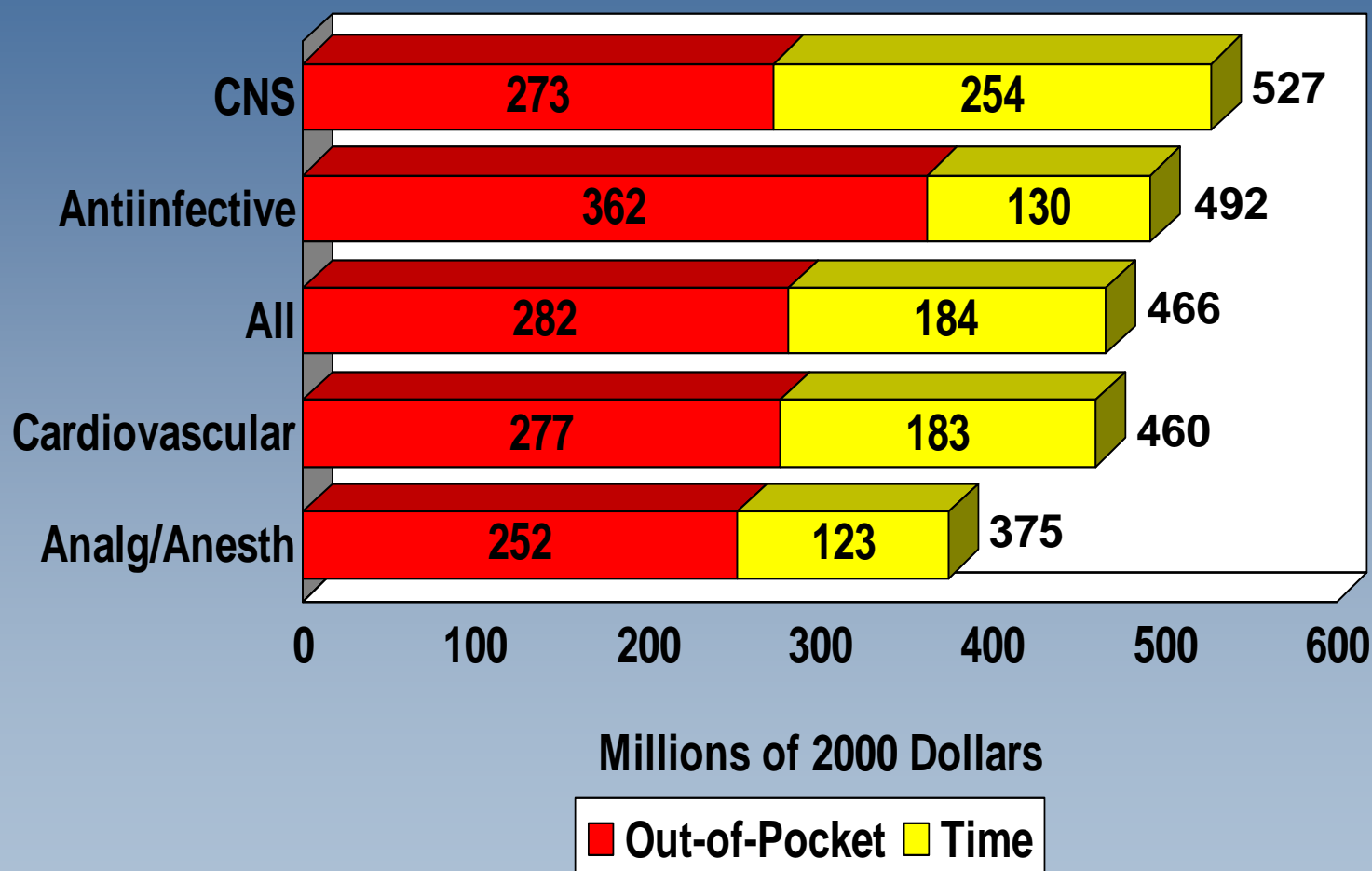
Source: DiMasi et al., *J Health Economics* 2003;22(2):151-185

# Compound Annual Growth Rates for Out-of-Pocket R&D Costs



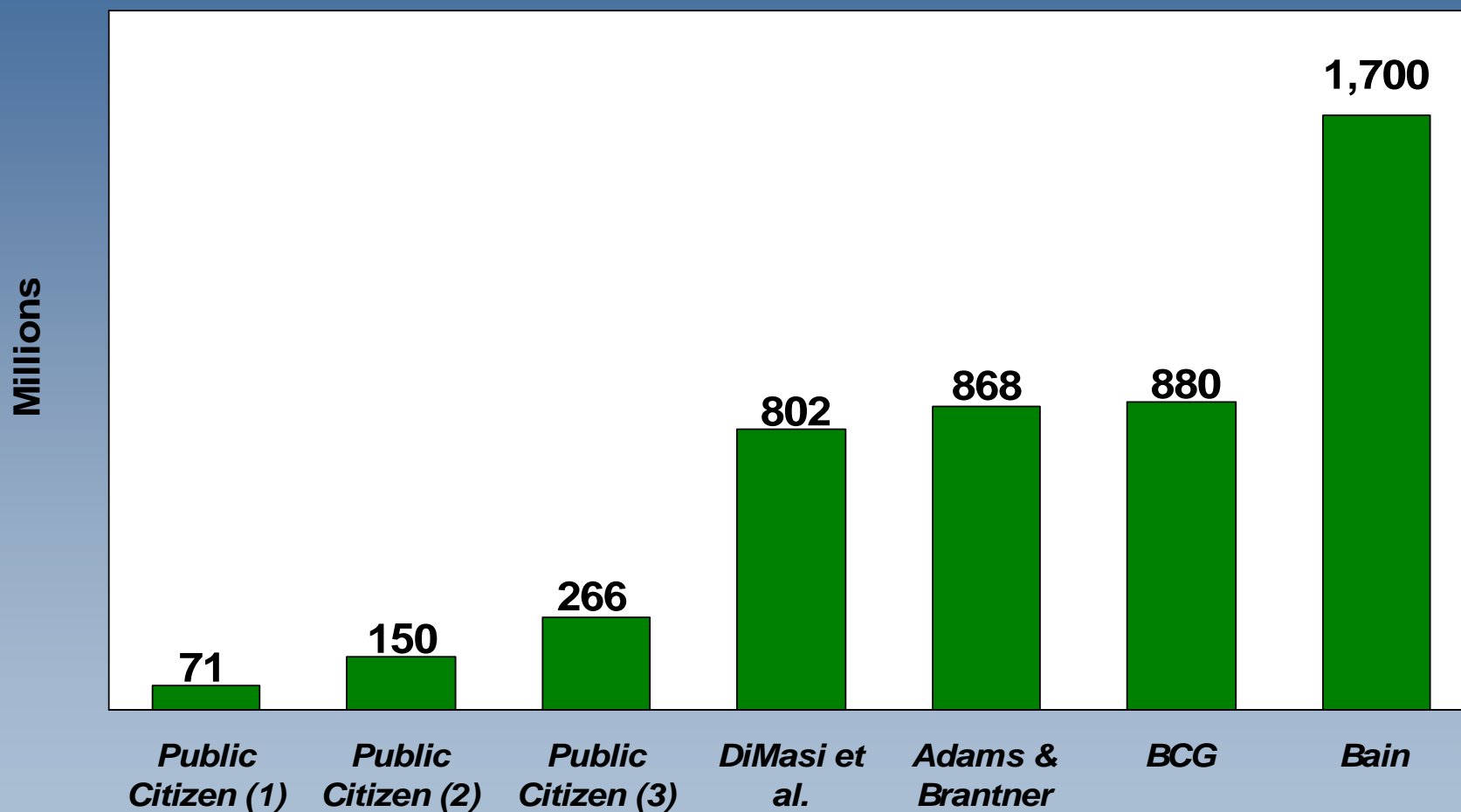
Source: DiMasi et al., *J Health Economics* 2003;22(2):151-185

# Clinical Cost per Approved New Drug by Therapeutic Category



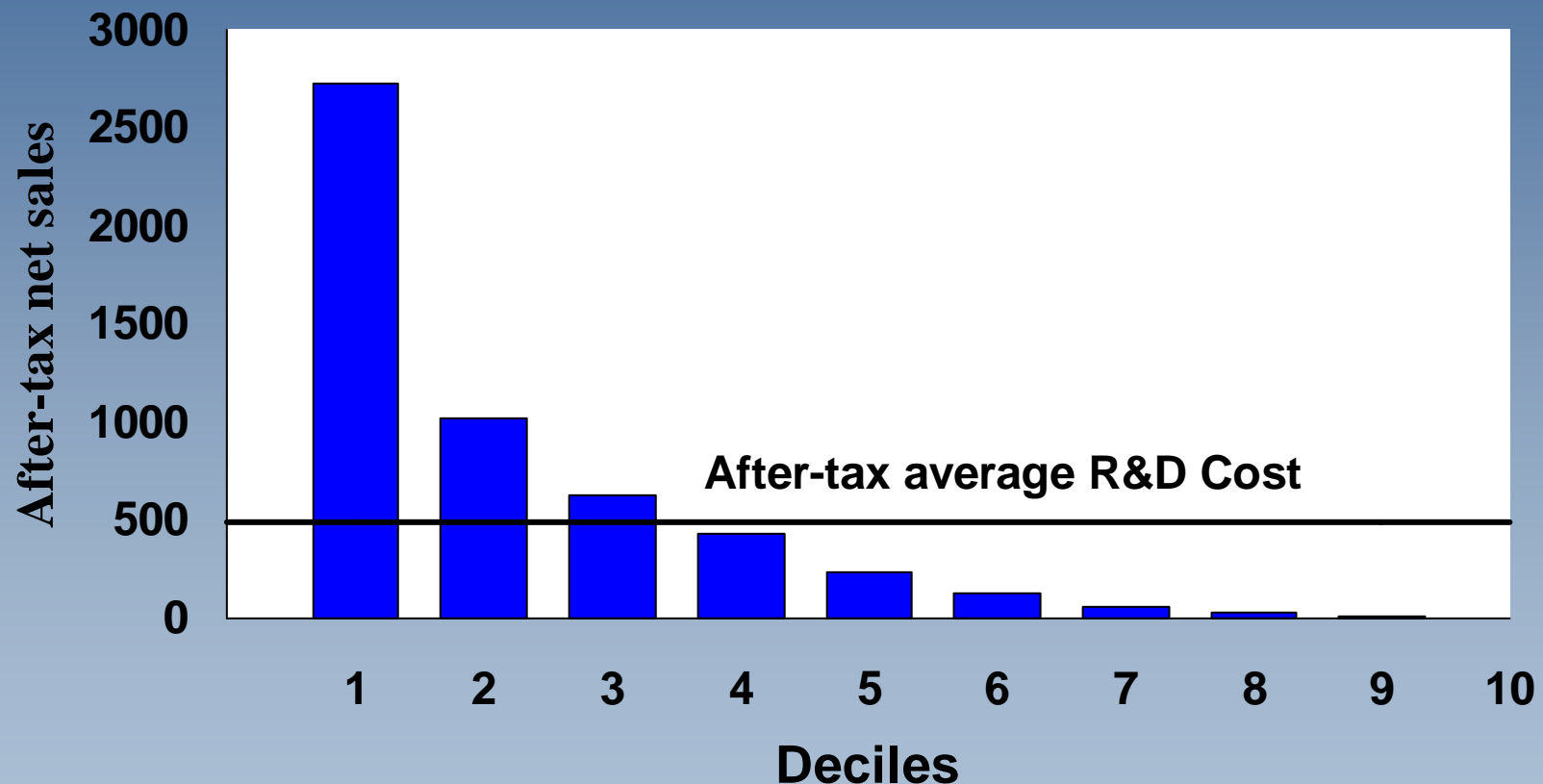
Source: DiMasi et al., *Drug Information Journal*, 2004;38(3):211-23

# Various Recent Estimates of New Drug Development Costs





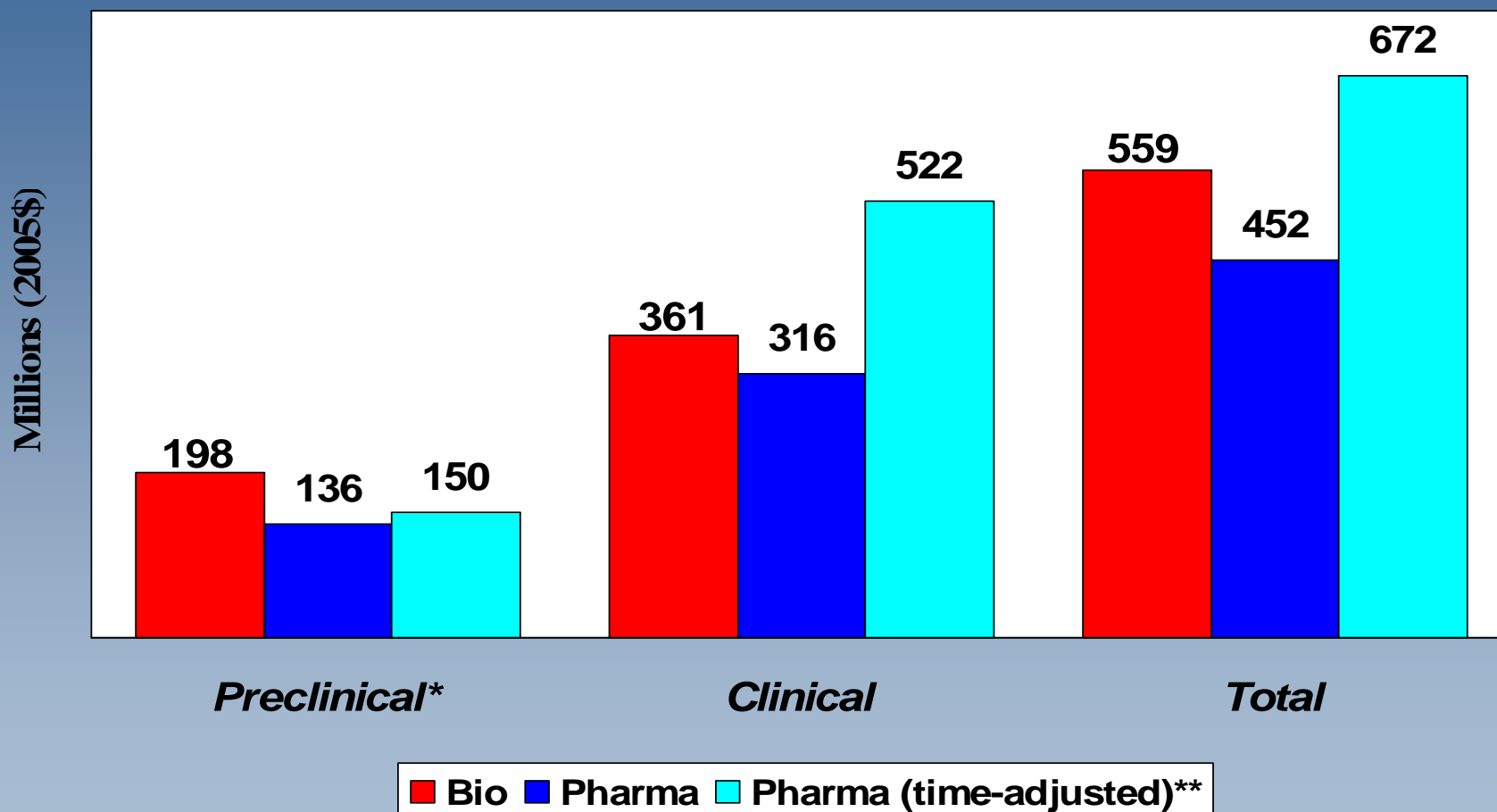
# Present Values of Net Sales and R&D Cost for New Drugs by Sales Decile (millions of 2000 \$)



Source: Grabowski et al., *PharmacoEconomics* 2002; 20(Suppl 3):11-29



# Biopharmaceutical Pre-Approval Out-of-Pocket Cost per Approved New Molecule

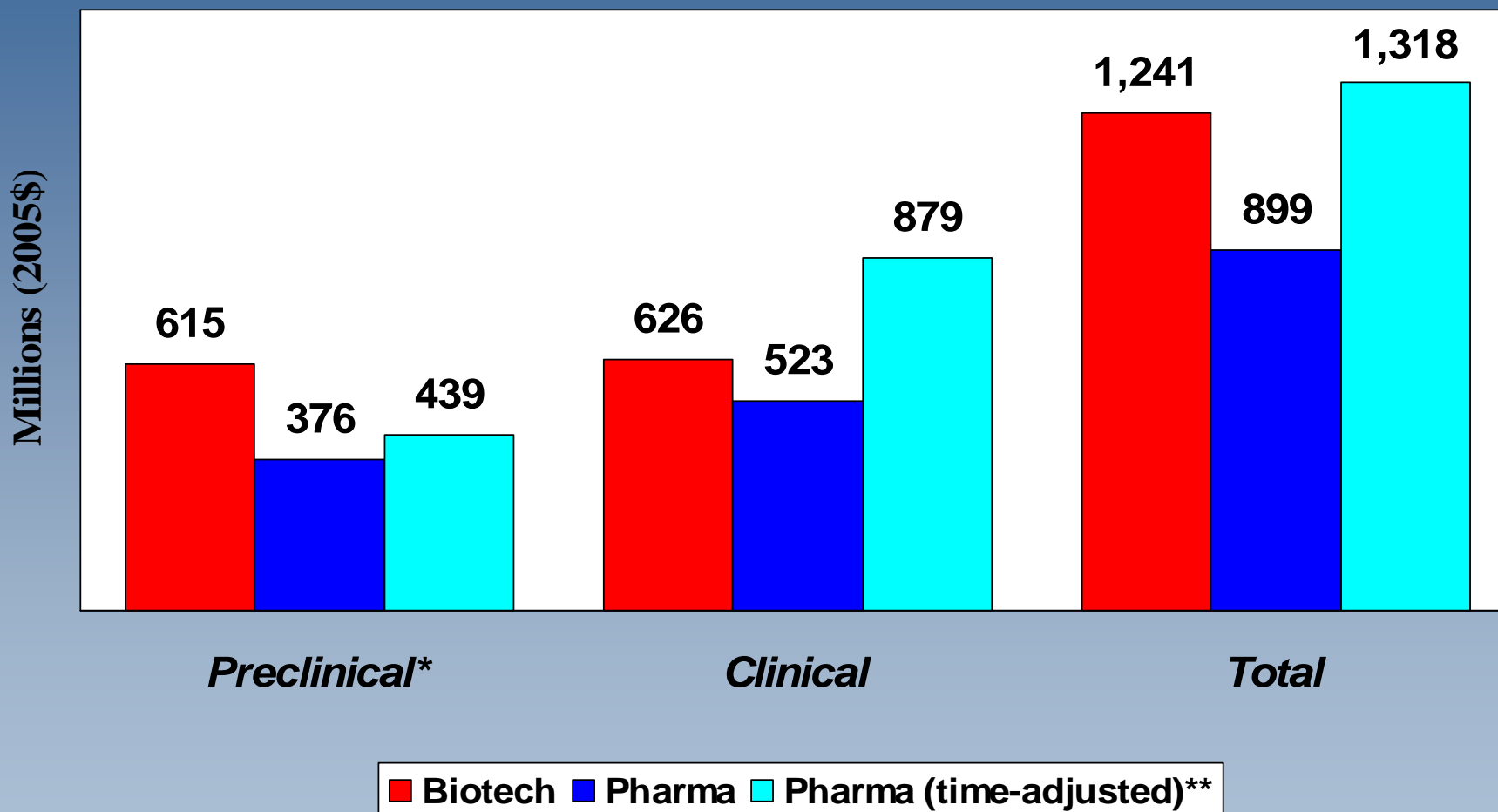


\* All R&D costs (basic research and preclinical development) prior to initiation of clinical testing

\*\* Based on a 5-year shift and prior growth rates for the preclinical and clinical periods

Source: DiMasi and Grabowski, *Managerial and Dec Econ* 2006, in press

# Biopharmaceutical Pre-Approval Capitalized Cost per Approved New Molecule



\* All R&D costs (basic research and preclinical development) prior to initiation of clinical testing

\*\* Based on a 5-year shift and prior growth rates for the preclinical and clinical periods

Source: DiMasi and Grabowski, *Managerial and Dec Econ* 2006, in press